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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/806,930 | 03/22/2004 | Sergey Anatolievich Lukyanov | CLON-094 | 2888 |

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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,930

Applicant(s)

LUKYANOV, SERGEY
ANATOLIEVICH

Examiner

Robert B. Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Handwritten signature/initials

DETAILED ACTION

This Office action is in response to the amendment filed March 21, 2005. **Claims 1-10 and 17-26** as drawn to elected Invention are currently pending and are under examination.

Priority

Applicants state that they are in disagreement with the examiner with regards to inadequate support for "a nucleic acid molecule encoding a polypeptide product comprising a first and second chromo/Fluorescent domain that are from *Cnidarian* species, e.g., *Anthozoan* species" in provisional applications 60/356,225, 60/383,336 and the non-provisional application 09/976,673. Applicants urge that the reason for this disagreement is because all the mentioned applications disclose the working example Cr-44-9, which is a tandem linked dimer encoding a first and second chromo/Fluorescent domain from a *Cnidarian*.

Applicants arguments have not been found persuasive because even though the mentioned applications provide written description for Cr-44-9, nowhere in the disclosure of the mentioned applications is there a statement regarding the fact that the sequences encode proteins from *Cnidarian* species, e.g., furthermore the examiner would like to point out that the claims are drawn to nucleic acid molecules encoding a polypeptide product comprising a first and second chromo/Fluorescent domain that are from *Cnidarian* species and not a linked dimer represented by Cr-44-9.

In conclusion the priority request in regards to "a nucleic acid molecules encoding a polypeptide product comprising a first and second chromo/Fluorescent domain that are from *Cnidarian* species" has only been granted to International application PCT/US02/32560, which is October 10, 2002

Withdrawal of Objections and Rejections

The objection to the specification because of sequence noncompliant issues is withdrawn.

The objection to claims 1-3 and 19-21 for failing to italicize species/family name is withdrawn.

Maintenance of rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-4 and 19-21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was explained in the previous Office action.

Claim Rejections - 35 USC § 102

Claims 1-10 and 17-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/27150.

This rejection was explained in the previous Office action.

Response to applicant's arguments

In view of the rejection of **claims 3-4 and 19-21** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the applicant urges that the specification provides multiple representative examples, including working examples of representative nucleic acids encoding exemplary mutant proteins, such that one of skill in the art would have no doubt that the applicant was in possession of the invention as claimed at the time the application was filed.

Applicant urges further that "the law is clear that, if a person of ordinary skill in the art would have understood the inventor to have possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met.

Applicants' arguments have not been found persuasive. In regards to nucleic acid molecules encoding a mutated polypeptide comprising a first and second chromo/Fluorescent domain that are from *Cnidarian* species, the applicant has not provided any direct support or description in the specification of the present application. On page 38 of the specification, under the title of Plasmid construction, the applicant describes the preparation of nucleic acid molecules that have been used to make vector constructs for fusion plasmids; however the applicant does not describe if these are mutated nucleic acids or the full length sequences. The applicant assumes that the information supplied in the subsequent examples is sufficient for a person skill in the art to determine how the full-length nucleic acid molecules were altered in order to give rise

to the fusion proteins of the invention. The working examples that the applicant speaks of are altered *Cnidarian* proteins that have been placed in a hybrid polypeptide construct, the applicant has failed to described how the original nucleic acid molecules were altered in order to give rise to a nucleic acid molecule encoding mutated chromo/fluorescent domain form a chromo/fluorescent protein form *Cnidarian* species. The applicant is reminded that the reason behind this argument is completely in line with applicants' own statement made on the record, on page 11, lines 1-4 of Response filed March 12, 2005, wherein applicants state that "the cited reference discloses nucleic acids encoding chromo/fluoroprotein mutants that exhibit different spectral properties than the wild type chromo/fluoroprotein". So clearly, as stated mutants can have different properties than the wild type, to an extent, which the mutant may not longer, have the same function as the wild type. If the applicant is claiming that the functional characteristics of the wild type construct are still associated with the mutant then there needs to be an explanation as to which region of the construct is responsible for the functional characteristics, as correctly stated previously by the applicants, not all mutants will display the same properties as the wild type and therefore it would be accurate to state that only the mutants containing the coding region responsible for the activity of the polypeptide will have the identical characteristics as the wild type. A person skill in the art would not know the difference between a nucleic acid molecule encoding a mutant polypeptide that has the same activity as the wild type from a mutant polypeptide that does not have the same activity of the wild type unless he was aware

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of the nucleic acid region that was responsible for the functional characteristics of the polypeptide.

In regards to the rejection of **claims 1-10 and 17-26** under 35 U.S.C. 102(b) as being anticipated by WO 01/27150, the applicants urge that Lukyanov et al. was not published more than one year earlier than the earliest priority date of the present application since, as discussed previously, the earliest priority date of the present application is October 12, 2001. The applicants urge further that Lukyanov et al., disclose nucleic acids encoding chromo/fluoroprotein mutants that exhibit different spectral properties than the wild type chromo/fluoroprotein and that Lukyanov et al. is silent as to the polypeptides comprising a first and second chromo/fluorescent domain.

Applicants' arguments have not been found persuasive. As stated previously in the priority section of the present Office action, the present CIP application has a priority date that, with regards to a nucleic acid molecule encoding a polypeptide product comprising a first and second chromo/Fluorescent domain that are from *Cnidarian* species, e.g., *Anthozoan* species, only goes as far as the filing date of International application PCT/US02/32560, which is October 10, 2002.

Furthermore it must be noted that the claims are drawn to a nucleic acid molecule encoding a polypeptide product comprising a first and second chromo/Fluorescent domain that are from *Cnidarian* species, Lukyanov et al. might be silent as to the specific nature of a polypeptide product comprising a first and second chromo/Fluorescent domain that are from *Cnidarian* species but is not silent in regards to a nucleic acid molecule encoding a polypeptide product comprising a first and second

chromo/Fluorescent domain that are from *Cnidarian* species. The applicant is reminded that the claims are drawn to a nucleic acid product that encodes a polypeptide and not the reverse: a polypeptide that is encoded by a nucleic acid molecule.

The examiner would also like to kindly point out to the applicant that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).

Claim 1 of the present application is written broadly to the extent that it reads on any nucleic acid molecule encoding a polypeptide product comprising a first and second chromo/Fluorescent domain that is from *Cnidarian* species. As indicated in the previous Office action the disclosure of WO 01/27150 provides all the mentioned limitations. The specific characteristics of the polypeptides disclosed in the examples of the present application are disclosed in the specification and not in Claim 1, if the applicant feels that the nucleic acid molecule (designated as SEQ ID NO: 1) encoding the fusion construct Cr-44-9 (designated as SEQ ID NO:2) is pertinent to the analysis of the claims they are more than welcome to amend the claims to include the mentioned specific embodiment.

Conclusion

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

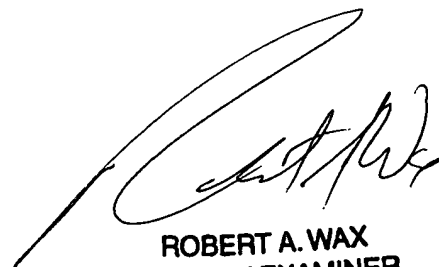
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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05-25-06


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